

## REMARKS

### The Office Action

Claims 26-63 are pending. Claims 28-46 stand rejected for indefiniteness. Claims 26-50 stand rejected for including new matter. Claims 51-63 are allowable.

### Rejections of Claims 26-50

Applicants have cancelled claims 26-50, and the rejections of these claims are now moot.

### Support for the Amendments

Claims 51 and 52 have been amended so that “R” can be a hydrogen. This amendment is supported by Figures 7 and 8 of the specification. The phrase “*two or more Rs are...*” is supported by original claim 1 and page 6, lines 17-18.

Claims 64-66 are supported by original claims 1, 5, 12, and 15 and Figures 7-16. Further support for claim 64 is found, for example, at page 10, line 2 to page 11, line 1 in combination with Example 10 and page 8, lines 4-31. Applicants note that one skilled in the art would readily recognize from reading these passages that Applicants invented polyalkylenimines having two or more tetraethylenepentamine or spermine structures with two or more hydrophobic groups at a degree of alkylation of less than or equal to 24.5%. (Applicants need not utilize any particular form of disclosure to describe the subject matter claimed, but applicants’ specification “must ‘convey clearly’ to those

skilled in the art to whom it is addressed...the information that [the inventor] has invented the specific subject matter later claimed.” *Martin v. Mayer*, 853 F.2d 500, 3 U.S.P.Q.2d 1333 (Fed. Cir 1987)). In addition, the “two or more” in Claim 64(i) is also supported by the formula (I) of the original claim 3, in which X<sup>m</sup> represents an “*arbitrary natural number*” (M.P.E.P. § 2163.05(III)). Moreover, the degree of alkylation recited in claim 64 is supported, for example, by compounds 1-10 in Figures 7 and 8.

Claim 67 is supported by original claim 2. Claim 68 is supported by the following description in the specification:

Any hydrophobic group that improves affinity between polyalkylenimine and phospholipid can be used as a hydrophobic group that is introduced into polyalkylenimine. For example, a cholesterol residue, a saturated or unsaturated alkyl group, or a saturated or unsaturated acyl group, a saturated or unsaturated acyloxycarbonyl group, or a phospholipid residue can be used. Preferably an octyl group, a cetyl group, a stearyl group, and an oleyl group can be used. (page 10, lines 24-31)(*underline added*)

Claims 69-71 are supported by the following description in the specification:

The average molecular weight among polyethylenimines used in the present invention is usually 200 to 1,000,000, and preferably 300 to 500,000, and more preferably 500 to 100,000. (page 10, lines 19-22)(*underline added*)

Only an upper range is given in claims 69 and 70, as the limitation “two or more tetraethylenepentamine or spermine structures” in claim 64 provides a lower limit to the molecular weight. Claims 72 and 73 are supported by original claims 5 and 12, respectively, and claims 74-81 are supported by original claims 18-25.

### New Claims

Applicants have amended claims 51 and 52 and added new claims 64-81. Claims 51 and 52, as amended, remain patentable over the cited art. Claims 64-81 recite compounds, e.g., as synthesized in the Examples of the specification, having at least two tetraethylenepentamine or spermine structures and a degree of alkylation of less than or equal to 24.5%. For example, compounds 2-10 of the Examples have at least two tetraethylenepentamines, compounds 22-27 have three tetraethylenepentamines, compounds 36-43 and 45-47 have three spermines, and compounds 48 and 49 have five spermines. None of prior art cited in the Office Action dated August 29, 2001 (i.e., Khmelnitsky, Byk, and Wolff) describes such compounds. For example, Khmelnitsky describes CEPEI having a degree of alkylation of 70% (pg. 740, second column). Byk's compounds, shown in columns 9-22 of the US patent document, have only one spermine. In Wolff, compounds 13 and 16 in columns 12 and 13 have only one tetraethylenepentamine, and the compounds shown in columns 10-17 have neither tetraethylenepentamine nor spermine. Therefore, the composition of claim 64 is distinct from the compositions disclosed in Khmelnitsky, Byk, and Wolff.

## CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for reply for one month, to and including June 24, 2004. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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